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A Comparative Study of Post Operative Analgesic Effect of Intra-Articular Levobupivacaine and Levobupivacaine with Fentanyl in Arthroscopic Knee Surgery

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ABSTRACT

Introduction: *This study was undertaken to compare and evaluate the analgesic efficacy between levobupuvacaine and levobupivacaine - fentanyl combination for post operative pain relief after arthroscopic knee surgery .*

Aims to compare total rescue analgesia requirement in first 24 hrs in these two groups and compare the adverse effects.

Methodology: *66 adult patients randomly allocated in two groups to received 20 ml 0.5% levobupivacaine with 1ml normal saline and 20ml 0.5% levobupivacaine with 1ml fentanyl.*

At the end of arthroscopic procedure done under general anesthesia before port closure, study drugs were administered. Intramuscular Diclofenac 75mg uses as rescue analgesic when VAS>4.

Results: *Time of rescue analgesia in Group A was 335.75±30.39 minutes compared to Group B 373.81±25.70 minutes. Total rescue analgesia in Group A were 1.687±0.4709 compared to Group B;1.39±0.4961. No adverse effects observed .*

Conclusion: *Intra-articular levobupivacaine with fentanyl is more efficacious than levobupivacaine alone.*

KEYWORDS : Post operative pain relief, intra articular , Levobupuvacaine, levobupivacaine with fentanyl , knee surgery

Introduction: Arthroscopic knee surgery is the one of the most common minimally invasive surgical procedure in modern orthopedic setup. It has been reported that a significant number of patients have moderate to severe pain 24 hours after ambulatory surgery in general and knee arthroscopy in particular,[5,6] and pain affects the patient's activity level and satisfaction.[6] Intra-articular administration of local anesthetic drugs provide adequate but short lived analgesia.[21] Therefore, different authors have tried various adjuvant agents with local anesthetics.[19] Early rehabilitation after arthroscopic knee surgery requires the use of effective methods for postoperative pain control. So in an attempt to improve the results, research has been directed toward new techniques for postoperative analgesia.

Aims was to compare and evaluate the efficacy of levobupuvacaine alone versus levobupivacaine with fentanyl in providing adequate analgesia after arthroscopic knee surgery.

Objectives were to compare the postoperative depth and duration of analgesia between two group , to compare total rescue analgesia requirement in first 24 hrs, to compare the adverse effects like hemodynamic instability, sedation, nausea, vomiting, itching, urinary retention between the two groups after intra-articular administration.

Methods : After obtaining approval of I EC clearance and informed consent from of sixty six, adults patients of ASA physical status I & II showing no gross clinical abnormality in systemic and laboratory examinations, not received analgesics in any form within 24 hours were included in the study. Patients with history of hypersensitivity to the study drugs, with contraindicated for spinal anesthesia and refusal for subarachnoid block were excluded for the study.

Sample size calculation done based on continuous response variable (mean duration of postoperative analgesia after knee arthroscopy and time to request for 1st dose rescue analgesic) from independent experimental. Mean time to postoperative analgesia and standard deviation values were assumed. Assuming a within group standard deviation of 40 minutes and the true difference in mean time to requirement of 1st dose rescue analgesic to be 30 minutes, we will need to study 33 experimental subjects per group to be able to reject the null hypothesis that the population means of the groups are equal with probability (power) of 0.85. The Type I error probability associated with this test of this null hypothesis is 0.05.

For this Prospective randomized double blinded study, a total of Sixty six patients were randomly allocated in two groups , Group A (n=33) - I received 20 ml of 0.5% levobupivacaine with 1ml normal saline and Group B (n=33) -I received 20 ml of 0.5% levobupivacaine with 1ml fentanyl .

Parameters studied for first post operative analgesic request (main variable), post operative depth of analgesia by VAS score in first 24 hrs (VAS recoded at 1st, 2nd, 4th, 6th, 12th & 24th hrs after discharging the patients from the operating room), total number of doses of analgesic requirement in first 24 hrs. Hemodynamic parameterscontinuously recorded for NIBP, MAP, SBP, DBP, HR, RR, SPO2 & ECG. Any adverse effect noted like nausea, vomiting, drowsiness, skin rash, allergic reaction, muscle weakness, bradycardia, hypotension, itching, urinary retention..

The anesthetic technique was standardized for all patients. Surgery was done under general anesthesia in conventional manner by inj propofol 2 mg/kg, inj fentanyl 2 mcg/kg, inj succinylcholine 2 mg/kg

followed by inj vecuronium 0.1mg/kg. Anesthesia was maintained by N2O:O2 (in 2 : 1 ratio) and vecuronium (top up doses as required). At the end of surgery before skin closure, study drug prepared was administered by the surgeon through port site in the intra-articular space. Tourniquet was kept inflated for another 20 minutes. Drain put by the surgeon was clamped before administering the study drug and remained clamped for another 20 minutes. The patients was be reversed by inj neostigmine 0.05 mg/kg along with inj atropine 0.02 mg/kg. VAS Scale was explained to the patients. HR, NIBP, RR, SPO2, ECG and pain VAS will be recorded at 1st, 2nd, 4th, 6th, 12th and 24th post operative hrs. Injection diclofenac sodium (75mg IM) was given as rescue analgesic if the pain VAS>4. First postoperative analgesia request time, total diclofenac used in first 24 hours was recorded. All data was collected by an observer who was unaware of patients' group assignment.

All data were entered into a MS Excel spreadsheet and analyzed using standard statistical software. Categorical variables were analyzed using the Pearson's chi square test. Normally distributed continuous variables were analyzed using the one way student t test. Non normal continuous variables were analyzed using the Kruskall Wallis H test. Numerical data were expressed as mean and standard deviation. Categorical variables were expressed as percentages. P value <0.05 was considered as significant.

Results:

The two groups were studied for patient's characteristics like demographic parameters (age, sex, height, body weight) and duration of surgery. First postoperative analgesia request time, total rescue analgesic used in first 24 hours, Visual Analogue Scale (VAS) score and side effects were recorded at 1st, 2nd, 4th, 6th, 12th and 24th post operative hours.

The mean age, the mean body weight in kg, height in centimetre of study population in two groups, percentage of male and female population, the mean duration of surgery were comparable between the two groups.

Time for the request of first post operative rescue analgesia in Group A (335.75±30.39 minutes) was shorter compared to Group B (373.18±25.70 minutes) (P<0.05) (Table 1).

Table 1.

Parameter	Group	Mean	Standard Deviation	Significance
Time of first post operative analgesic request	**Group A (Levobupivacaine)**	335.75	30.39	<0.001
	Group B (Levobupivacaine+Fentanyl)	373.18	25.70	

Table 1. Showing the mean duration of post operative analgesia in minutes and their standard deviation and significance level of the study groups.

Total number of rescue analgesia requirement in first 24 hours in postoperative period was also more in Group A (1.68±0.470) compared to Group B (1.39±0.496) (P>0.05) (Table 2).

Table 2.

Parameter	Group	Mean	Standard Deviation	Significance
Number of rescue analgesic requirement in post operative 24 hours.	**Group A (Levobupivacaine)**	1.687	0.470	0.015
	Group B (Levobupivacaine+Fentanyl)	1.393	0.496	

Table 2.Showing the mean number of dose of rescue analgesic requirement in first post operative 24 hours and their standard deviation and significance level

Table 3.

Parameter	Group	Mean	Standard Deviation	Significance
VAS at 1st post operative hour	Group A (Levobupivacaine)	0	0	1
	Group B (Levobupivacaine+Fentanyl)	0	0	
VAS at 2nd post operative hour	Group A (Levobupivacaine)	0.606	0.863	<0.001
	Group B (Levobupivacaine+Fentanyl)	0	0	
VAS at 4th post operative hour	Group A (Levobupivacaine)	2.848	0.833	<0.001
	Group B (Levobupivacaine+Fentanyl)	1.939	0.609	
VAS at 6th post operative hour	Group A (Levobupivacaine)	1.212	1.19	< 0.001
	Group B (Levobupivacaine+Fentanyl)	3.878	.857	
VAS at 12th post operative hour	Group A (Levobupivacaine)	2.030	0.394	0.0096
	Group B (Levobupivacaine+Fentanyl)	1.757	0.435	
VAS at 24th post operative hour	Group A (Levobupivacaine)	1.909	1.259	< 0.001
	Group B (Levobupivacaine+Fentanyl)	3.151	1.460	

Visual Analogue Scale (VAS) score (mean, Standard Deviation and their significance level) of the study Groups (A, B) at 1st, 2nd, 4th, 6th, 12th and 24th post operative hours

Table-3 showing the Visual Analogue Scale (VAS) score (mean, Standard Deviation and their significance level) of the study Groups (A, B) at 1st, 2nd, 4th, 6th, 12th and 24th post operative hours. The VAS score was 0 in all the groups at 1st post operative hour. Compared with Group A, Group B had higher mean VAS score at 6th and 24th postoperative hours (Figure-19 and Figure-20 respectively).

No incidence of adverse effects like nausea, vomiting, urinary retention, itching or sedation was observed in any one in the study population.

Discussion: . Intra-articular drug administration is one of the simplest techniques requiring no specialized equipment for pain management.78 But intra-articular drug administration is possible only when the patient undergoes surgery Satisfactory results have emerged from different studies of intra-articular administration of small systemically inactive doses of narcotics during arthroscopic knee surgery.

In this study, sixty six patients underwent arthroscopic knee surgery were randomly assigned into two groups (A and B) in a double blinded fashion

Time for the request of first post operative rescue analgesia in Group A (335.75±30.39 minutes) was shorter compared to Group B (373.81±25.70 minutes) (P<0.05) (Table 1.). Total number of rescue analgesia requirement in first 24 hours in postoperative period was also more in Group A (1.687±0.4709) compared to Group B (1.39±0.4961) (P>0.05) (Table 2).

Table- 3 shows the Visual Analogue Scale (VAS) score (mean, Standard Deviation and their significance level) of the study Groups (A and B) at 1st, 2nd, 4th, 6th, 12th and 24th post operative hours. The VAS score was 0 in all the groups at 1st post operative hour. Compared with Group B, Group A had lower mean VAS score at 6th and 24th postop-

erative hours (Figure-19 and Figure-20). This lower mean VAS score at 6th and 24th postoperative hours in levobupivacaine group was probably due to administration of rescue analgesia in before the time of scheduled observation.

No incidence of adverse effects like nausea, vomiting, urinary retention, itching or sedation was observed in any one in the study population.

CONLUSION

From the results of our study it was clearly found that analgesic efficacy of intra-articular levobupivacaine with fentanyl is superior than only levobupivacaine. However, further clinical studies can be performed to develop a more reliable and clinically efficient regime of levobupivacaine so that, this regime can be used effectively as a component of multimodal approach of post operative analgesia without any side effects.

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